

REMARKS

The present application was filed on July 25, 2001 having claims 1-17. Claims 1-17 remain pending in the application.

In the Office Action dated January 10, 2003, the Examiner: (1) rejected claims 1-8 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 3,839,297 to Wasserman et al.; and (2) rejected claims 9-17 under 35 U.S.C. §103(a) as obvious over Wasserman et al.

With respect to claims 1-8, applicants respectfully traverse the rejection under 35 U.S.C. §102(b) in view of Wasserman et al. According to the Examiner,

[t]he cited prior art discloses a copolymer of lactide and glycolide comprising at least 65 mol% lactide and no more than 35 mol% of glycolide, said copolymer being made using stannous octoate catalyst. . . . The copolymer has an IV of about 1.4 and patentees further disclose that when stannous octoate is used as the catalyst the molecular weight increases and the molecular weight distribution decreases.

(See January 10 Office Action at page 2.)

However, nowhere does Wasserman et al. disclose a “composition of matter comprising a batch copolymer, the copolymer containing repeating units derived from glycolide and repeating units derived from lactide, wherein said batch possesses an inherent viscosity in the range of from about 1.30 to about 1.55, and wherein the standard deviation of inherent viscosity measurements from 10 or more random samples selected from within the batch is about 0.05 or less” as required by independent claim 1.

Moreover, nowhere does Wasserman et al. disclose a “composition of matter comprising a copolymer containing repeating units derived from glycolide and repeating units derived from lactide, the copolymer having a BVD of about 0.05 or less” as

required by independent claim 8 (BVD is defined at pages 5-6 of the specification as “batch viscosity deviation” and refers to the standard deviation of at least ten measurements of inherent viscosity on ten differently randomly selected samples from a single batch of copolymer).

In fact, as acknowledged by the Examiner at page 3 of the Office Action, Wasserman et al. does not disclose a standard deviation of the inherent viscosity measurements.

In an attempt to remedy the deficiencies of Wasserman et al., the Examiner asserts that the claimed standard deviation of the inherent viscosity measurements would be an inherent feature of the Wasserman et al. copolymer. (See Office Action at page 2.) However, according to Federal Circuit decisions an anticipatory inherent feature or result (such as applicants’ recited standard deviation) must be consistent, necessary and inevitable, not merely possible or probable. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

There is no evidence whatsoever that the recited “standard deviation of inherent viscosity” would be a consistent, necessary and inevitable result from any polymerization process, and certainly no evidence that the processes disclosed by Wasserman would consistently, necessarily and inherently provide a copolymer having the recited standard deviation of inherent viscosity. To the contrary, evidence of record establishes unequivocally that not all polymerization processes provide the recited narrow standard deviation.

Specifically, the data in applicants' Comparative Example A clearly establishes that not all polymerization reactions of lactide and glycolide will, in fact, result in a batch copolymer possessing "an inherent viscosity in the range of from about 1.30 to about 1.55, and wherein the standard deviation of inherent viscosity measurements from 10 or more random samples selected from within the batch is about 0.05 or less" as required by claim 1. Nor will every polymerization reaction necessarily result in a batch copolymer "having a BVD of about 0.05 or less" as required by claim 8.

As applicants' comparative data clearly establishes, the narrow standard deviation of inherent viscosity as claimed by applicants is not present in all polymerization reactions of glycolide and lactide in the presence of a stannous octoate catalyst.

Because the evidence of record shows that not all polymerization processes will consistently, necessarily and inevitably provide the recited standard deviation of inherent viscosity, there is absolutely no basis in fact for concluding or even suggesting that the process disclosed by the applied Wasserman reference will consistently, necessarily or inevitably provide product having the recited characteristics. Accordingly, independent claims 1 and 8 are believed to be patentably distinct from the Wasserman et al. patent. Claims 2-7, which depend directly from independent claim 1, are also believed to be allowable over the cited reference. Therefore, in view of the above remarks, reconsideration of this rejection is respectfully requested.

Claims 9-17 were rejected under 35 U.S.C. §103(a) as obvious over Wasserman et al. This rejection is respectfully traversed. As noted above, while the Examiner acknowledges that Wasserman et al. fails to disclose a standard deviation of inherent viscosity measurements, the Examiner asserts this characteristic is obvious. However,

the standard deviation recitation of applicants' claim 9 which the Examiner asserts is obvious is included in a drying step that is completely absent from Wasserman et al. Specifically, claim 9 includes the following final step:

drying the polymeric resin in an inert gas atmosphere and under a reduced pressure of no more than about 20 torr psia by maintaining the polymeric resin at ambient temperature for at least about 4 hours, then raising the temperature of the polymeric resin to a drying temperature of at least about 120°C. to about 130°C. at the rate of from about 1°C. to about 3°C. per hour, then maintaining the drying temperature of the polymeric resin for at least about 48 hours to produce a batch of an absorbable polymeric resin having an inherent viscosity characterized by a standard deviation of about 0.05 or less.

In order to establish the *prima facie* obviousness of a claim, "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." See MPEP §2143. Nowhere does Wasserman disclose or suggest the drying of its polymer in the manner recited in independent claim 9. Without such teaching or suggestion, there is no *prima facie* case of obviousness.

Moreover, as noted above and contrary to the Examiner's assertions, applicants' comparative data clearly establishes that not all polymerization reactions of lactide and glycolide will, in fact, result in a "batch of an absorbable polymeric resin having an inherent viscosity characterized by a standard deviation of about 0.05 or less" as required by claim 9.

Accordingly, claim 9 is believed to be patentably distinct from the Wasserman et al. patent. Claims 10-17, which depend either directly or indirectly from independent claim 9, are also believed to be allowable over the cited reference. Accordingly, in view of the above remarks, reconsideration of this rejection is respectfully requested.

It is believed that the claims of the application as now presented, i.e., claims 1-17, are patentably distinct over the art of record and are in condition for allowance. In the event that the examiner believes that a telephone conference or a personal interview may facilitate resolution of any remaining matters, the undersigned may be contacted at the number indicated below. In view of the foregoing amendment and remarks, early and favorable reconsideration of this application is respectfully requested.

Respectfully submitted,



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